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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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1- File Copy

PTO-90C (Rev.11/00)

Office Action Summary	Application No. 09/645,835	Applicant(s) KEONING ET AL.
	Examiner Chih-Min Kam	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *9-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-8, drawn to polypeptides, classified in class 530, subclass 350.

II. Claims 9-10 and 14-16, drawn to polynucleotides and vectors, classified in class 530, subclass 23.1.

III. Claims 11-12, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claim 13, drawn to genetically engineered cells producing antibody, classified in class 435, subclass 71.1.

V. Claims 17-19, drawn to a vaccine composition comprising a polypeptide, classified in class 424, subclass 185.1.

VI. Claims 20-21, drawn to a method of vaccinating an animal, classified in class 424, subclass 185.1.

VII. Claims 22-24, drawn to a method of treating a disease comprising an antibody, classified in class 424, subclass 130.1.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Invention I are related to the polynucleotides of Invention II because the polynucleotides encodes the specifically claimed polypeptides. The inventions are distinct because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as synthetic peptide synthesis or purification from natural source. Further, the polynucleotides may be used for process other than the production of the polypeptide, such as nucleotide hybridization assay.

The polypeptides of Invention I are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the polypeptide and the antibody are related due to their complementary structures, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition or to assay or purify the cognate receptor of the polypeptide.

The polypeptides of Invention I are related to the cells of Invention IV because the polypeptides can be produced by the cells. The inventions are distinct because they are physically and functionally distinct chemical entities, and because the polypeptide can be made by another and materially different process, such as synthetic peptide synthesis or purification from natural source.

The polypeptides of Invention I are related to the vaccine composition of Invention V because the effective amount of polypeptides can be used to prepare the vaccine composition. The inventions are distinct because they are physically and functionally distinct chemical entities, and because the vaccine composition can be prepared by other materials such as retrovirus or bacterial antigen.

The polypeptides of Invention I are distinct from the methods of Inventions VI and VII, because the products of Invention I can be neither made by nor used in the methods of Inventions VI and VII.

The polynucleotides of Invention II are distinct from the products of Inventions III, IV, and V because they are physically and functionally distinct chemical entities.

The polynucleotides of Invention II are distinct from the methods of Inventions VI and VII because the products of Invention II can be neither made by nor used in the methods of Inventions VI and VII.

The antibodies of Invention III are related to the cells of Invention IV because the cells can produce the antibodies. The inventions are distinct because they are physically and functionally distinct chemical entities, and because the antibodies can be made by another and materially different process, such as purification from natural source.

The antibodies of Invention III are distinct from the products of Invention V because they are physically and functionally distinct chemical entities.

Inventions III and VI are independent and distinct because antibodies of Invention III can be neither made by nor used in the method of the Invention VI.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of invention VII can be practiced with other drugs such as antibiotics.

The cells of Invention IV are distinct from the vaccine compositions of Invention V because they are physically and functionally distinct chemical entities.

Inventions IV and VI, VII are independent and distinct because cells of Invention IV can be neither made by nor used in the methods of the Inventions VI and VII.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of invention VI can be practiced with other vaccine compositions such as retrovirus or bacterial antigen composition.

The products of Invention V are distinct from the method of Invention VII because the products of Invention V can be neither made by nor used in the method of Invention VI.

The method of Invention VI is distinct from the method of Invention VII because the two methods use separate method steps, active agents and have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because inventions I-VII require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

During a telephone conversation with Alan Grant on January 10, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Informalities

3. The disclosure is objected to because of the following informalities:

On page 28, lin16, there is URL in the form of a hyperlink and/or other forms of browser-executable code which is impermissible in the patent application and requires deletion.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph as being indefinite because of the use of the term "comprising an amino acid sequence at least 75% identical to a sequence selected from the group consisting of SEQ ID NO: 2, 4 and 6". The term "comprising an amino acid sequence at least 75% identical to a sequence selected from the group consisting of SEQ ID NO: 2, 4 and 6" renders the claim indefinite, it is unclear what kind of polypeptide is intended, especially where the polypeptide with only 75% identity does not have the activity of the polypeptide which is 100% identical to SEQ ID NO: 2, 4 or 6 nor is it clear whether or not the 75%, or 90% (claim 2) or 95%(claim 3) are contiguous or not. Claims 5-8 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend. In claim 5 and claims dependent thereto, it is not apparent how the peptide is "isolated" where as claimed it is "found" in a microorganism which contains DNA,

RNA, other proteins and inorganic components. Use "isolated from" rather than "found" (see claim 5 , line 1).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-3, 5 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Spellerberg *et al.* (Infection and Immunity 67, 871-868 (1999)).

Spellerberg *et al.* teach a putative lipoprotein from *Streptococcus agalactiae*, Lmb which exhibits significant homology to streptococcal protein LraI family mediates attachment of *Streptococcus agalactiae* to human laminin and has a peptide sequence of 822 amino acid residues (pages 871, 874-876, Fig. 1). Sequence alignment has shown that Lmb has 97.8% and 99.9% sequence homology to SEQ ID NO: 2 and 6, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spellerberg *et al.* in view of Bentle *et al* (US 4,694,073).

Spellerberg *et al.* teach a putative lipoprotein from *Streptococcus agalactiae*, Lmb mediates attachment of *Streptococcus agalactiae* to human laminin and has a peptide sequence of 822 amino acid residues (pages 871, 874-876, Fig. 1). The sequence alignment indicates that Lmb has 99.9% sequence homology to SEQ ID NO: 6 and has a Met at N-terminus (versus Val in SEQ ID NO: 6). However, Spellerberg *et al.* fail to disclose the exact sequence of SEQ ID NO: 6. Bentle *et al.* teach conservative substitutions such as substitution of aliphatic residues for one another (Ile, Val, Leu and Met) in Somatotropin do not cause substantial change in the gross chemical properties of a protein (col. 4, line 11-24). At the time of invention was made, it would have been obvious to one of ordinary skill in the art that the protein sequence taught by Spellerberg *et al.* to have modified the proteins of SEQ ID NO: 6 because one of ordinary skill in the art would have been motivated to verify the same activities of the two proteins.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/645,835
Art Unit: 1653

Chih-Min Kam, Ph. D.
Patent Examiner

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March 28, 2001

Christopher S. F. Low

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